UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ALLISON TICE, PLAINTIFF, vs. BOSTON SCIENTIFIC CORPORATION and JOHN DOES 1–3, DEFENDANTS.	)	CASE NO. 5:22-cv-763 JUDGE SARA LIOI **MEMORANDUM OPINION AND ORDER**

Before the Court is defendant Boston Scientific Corporation's ("Boston Scientific") motion to dismiss the complaint for failure to state a claim. (Doc. No. 4 (Motion).) Plaintiff Allison Tice ("Tice") filed an opposition (Doc. No. 9 (Opposition)), and Boston Scientific filed a reply (Doc. No. 10 (Reply)). For the reasons discussed herein, Boston Scientific's motion to dismiss is granted, but Tice is granted leave to amend her complaint.

I. BACKGROUND

Tice filed her complaint on June 3, 2021, in the Court of Common Pleas, Summit County, Ohio (Doc. No. 1-1 (Complaint)), alleging that a medical device (the Spectra SCS) produced by Boston Scientific was implanted in her spine on June 3, 2019, but failed on or about August 19, 2019, causing Tice "severe pain, bodily injuries and burns throughout" her body. (*Id.* ¶¶ 8, 14–16; *see also* Doc. No. 4-1, at 1.[1]) On May 11, 2022, Boston Scientific removed this action to federal court, invoking this Court's diversity jurisdiction.[2] On the same day, Boston Scientific filed the

[1] All page number references herein are to the consecutive page numbers applied to each individual document by the Court's electronic docketing system.

[2] Boston Scientific was not served with Tice's complaint until April 11, 2022. (Doc. No. 1 ¶ 1; Doc. 1-1, at 11.)

instant motion to dismiss. Tice filed an opposition and Boston Scientific filed a reply. The matter is now ripe for the Court's review.

II. STANDARD OF REVIEW

In the context of a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the sufficiency of the complaint is tested against the notice pleading requirements of Fed. R. Civ. P. 8(a)(2), which provides that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Although this standard is liberal, Rule 8 still requires a plaintiff to allege sufficient facts that give the defendant "fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346, 125 S. Ct. 1627, 161 L. Ed. 2d 577 (2005) (quotation marks and citation omitted). Thus, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true," to state a plausible claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct.1955, 167 L. Ed. 2d 929 (2007)).

A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Twombly*, 550 U.S. at 556). Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully.'" *Id*. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id*. at 679 (quoting Fed. R. Civ. P. 8(a)(2) (second alteration in original)). In such a case, the plaintiff has not

"nudged [his] claims across the line from conceivable to plausible, [and the] complaint must be dismissed." *Twombly*, 550 U.S. at 570; *see Iqbal*, 556 U.S. at 683.

A complaint need not set down in detail all the particulars of a plaintiff's claim. However, "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 556 U.S. at 678–79 (stating that this standard requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation"). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. at 678 (citing *Twombly*, 550 U.S. at 555). The complaint "must contain either direct or inferential allegations respecting all the material elements to sustain a recovery under *some* viable legal theory." *Scheid v. Fanny Farmer Candy Shops, Inc*., 859 F.2d 434, 436 (6th Cir. 1988) (internal quotations marks omitted) (emphasis in original), *abrogated on other grounds by Buckhannon Bd. & Care Home, Inc. v. W. Va. Dep't of Health & Human Res.*, 532 U.S. 598, 121 S. Ct. 1835, 149 L. Ed. 2d 855 (2001).

When resolving a motion to dismiss pursuant to Rule 12(b)(6), the Court may consider the complaint and any exhibits attached thereto, public records, items appearing in the record of the case, and exhibits attached to the defendant's motion to dismiss provided such are referenced in the complaint and central to the claims therein. *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008); *see also Stringfield v. Graham*, 212 F. App'x 530, 535 (6th Cir. 2007) (explaining that documents "attached to and cited by" the complaint are "considered parts thereof under Federal Rule of Civil Procedure 10(c)").

III. DISCUSSION

Although not clearly labeled, Tice contends that her complaint raises state-law claims of (1) strict liability,[3] (2) negligence,[4] (3) breach of implied warranty, (4) breach of express warranty, and (5) negligent misrepresentation.[5] (Doc. No. 9, at 3.) Boston Scientific contends that Tice's complaint must be dismissed because her claims are preempted by federal law. (Doc. No. 4 ¶ 1.) Notwithstanding federal preemption, Boston Scientific also contends that the complaint must be dismissed because it "only contains claims for common law product liability causes of action[,

[3] Tice's "strict liability" claim appears to be for manufacturing defect. (*See* Doc. No. 9, at 9 (contending the complaint alleges that the Spectra SCS was defective because it "deviated in a material way from its manufacturing performance standards").)

[4] Tice's "negligence" claim appears to be for failure to warn. (*See* Doc. No. 9, at 9 (referencing a "failure to warn" claim).)

[5] Although Tice contends in her opposition brief that her complaint sufficiently pled a claim for misrepresentation, she does not cite even a single allegation in the complaint to support that contention. (*See* Doc. No. 9, at 14–15.) As Tice acknowledges, under Ohio law, a negligent misrepresentation claim is one where a defendant

> who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their *justifiable reliance* upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

Delman v. City of Cleveland Hts., 534 N.E.2d 835, 838 (Ohio 1989) (quoting 3 Restatement of the Law 2d, Torts (1965) 126–27, Section 552(1)) (emphasis added in original) (additional citations omitted). Even viewing the complaint in a light most favorable to Tice, the Court could not find any allegations to support a negligent misrepresentation claim. Chiefly, there are no allegations concerning false statements by Boston Scientific—there are only allegations that Boston Scientific failed to provide enough information about potential risks. (*See, e.g.*, Doc. No. 1-1 ¶¶ 10, 12–13.) To the extent Tice is attempting to amend her complaint through her opposition brief, it is well established that a plaintiff cannot use that vehicle to amend the pleadings. *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 979 F.3d 426, 440 (6th Cir. 2020) ("As a general rule, a court considering a motion to dismiss 'must focus only on the allegations in the pleadings.' . . . This does not include plaintiffs' responses to a motion to dismiss." (quoting *Bates v. Green Farms Condo. Ass'n*, 958 F.3d 470, 483 (6th Cir. 2020))). As such, any claim for negligent misrepresentation must be dismissed.

which are] abrogated by the Ohio Product Liability Act" and because the complaint is "impermissible 'shotgun pleading[.]'" (*Id.* ¶¶ 2–3.)

A. Preemption Under the Medical Device Amendments

The Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, establishes various levels of oversight for medical devices depending on the degree of risk posed. Class III devices are subject to strict regulation by the Food and Drug Administration ("FDA") through a rigorous process known as "premarket approval" ("PMA"). *See* 21 U.S.C. § 360c(a)(1)(C); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001) ("Class III devices must complete a thorough review process with the FDA before they may be marketed."); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) ("[T]he 'premarket approval,' or 'PMA' process, is a rigorous one."). During the PMA review, a manufacturer must provide the FDA with a "reasonable assurance" that the device is safe and fit for human use. 21 U.S.C. § 360e(d)(2). In addition, the FDA's PMA review process includes weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id.* § 360c(a)(2)(C). After the PMA review concludes, the FDA grants or denies regulatory approval for the reviewed medical device. *Id.* § 360e(d).

Once a device has received premarket approval, it "may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. If the manufacturer wishes to make any such changes, it must submit, and the FDA must approve, an application for supplemental premarket approval ("PMA Supplement"). *See* 21 U.S.C. § 360e(d)(5); 21 C.F.R. § 814.39. The same procedures that apply to applications for a PMA also apply to applications for PMA Supplements. 21 C.F.R. § 814.39(c).

After premarket approval, a device is subject to continued reporting requirements. *See* 21 U.S.C. § 360i; 21 C.F.R. § 814.84. These requirements include the obligation to submit periodic reports to the FDA informing the agency of any "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device" as well as any "[r]eports in the scientific literature concerning the device" that the applicant knows of or reasonably should know of. 21 C.F.R. § 814.84(b)(2). The applicant also must report to the FDA no later than 30 days after "receiv[ing] or otherwise becom[ing] aware of information, from any source, that reasonably suggests that a device . . . (1) [m]ay have caused or contributed to a death or serious injury; or (2) [h]as malfunctioned and this device . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a)(1)–(2). The FDA has the power to withdraw premarket approval where it determines that a device is unsafe or ineffective, 21 U.S.C. § 360e(e)(1), and to order the recall of a device where there is a reasonable probability that the device would cause serious adverse health consequences or death. *Id.* § 360h(e).

The parties agree that the Spectra SCS implanted into Tice's spine was an approved Class III medical device under the MDA. (*See* Doc. No. 4-1, at 6; Doc. No. 9, at 2.) *See* 69 Fed. Reg. 58, 446–47 (Sept. 30, 2004) (listing the original April 27, 2004 PMA approval for the Spectra SCS). Further, the parties agree that Tice's state-law claims of strict liability, negligence, breach of implied warranty, and breach of express warranty are preempted under the MDA's express preemption clause, unless Tice's claims are premised on the Spectra SCS violating an FDA requirement for which there is a state law equivalent. (Doc. No. 4-1, at 13; Doc. No. 9, at 6–7.)

> The MDA's express preemption clause provides that
>
> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court has interpreted § 360k(a) to preempt most common-law tort duties. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323–25, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). The Court's reasoning was that state-law tort suits would interfere with the requirements that the FDA imposed for a particular device through the extensive PMA process for Class III devices like the Spectra SCS. That holding applies, however, "only to the extent that [the state-law requirements] are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). "Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*

In *Riegel*, the Supreme Court established a two-part test to determine if the MDA expressly preempts a state-law claim. First, a court must "determine whether the federal government has established requirements applicable to the medical device[.]" *White v. Medtronic, Inc.*, 808 F. App'x 290, 294 (6th Cir. 2020) (quoting *White v. Medtronic, Inc.*, No. 18-11590, 2019 WL 1339613, at *3 (E.D. Mich. Feb. 20, 2019) (citing *Riegel*, 552 U.S. at 321–22), *report and recommendation adopted*, No. 18-11590, 2019 WL 1330923 (E.D. Mich. Mar. 25, 2019)). All

PMA-approved medical devices, like the Spectra SCS, automatically fulfill this first step. *See Riegel*, 552 U.S. at 332 ("Premarket approval . . . imposes 'requirements' under the MDA . . . .").

Second, courts must "determine whether the state law claims are based upon requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness." *White*, 808 F. App'x at 294 (quoting *White*, 2019 WL 1339613, at *3) (citing *Riegel*, 552 U.S. at 321–22), *report and recommendation adopted*, No. 18-11590, 2019 WL 1330923 (E.D. Mich. Mar. 25, 2019)). "A claim premised upon a state law will be preempted where judges and juries [would be required] to second-guess the balancing of benefits and risks of a specific device to their intended patient population—the central role of FDA." *Mories v. Bos. Sci. Corp.*, 494 F. Supp. 3d 461, 468 (S.D. Ohio 2020) (internal quotation marks and citation omitted). "Conversely, if the state law provides a damages remedy for claims premised on a violation of the FDA regulations themselves, then the state duties parallel, rather than add to or deviate from, federal requirements." *Id.* (citing *Lohr*, 518 U.S. at 495).

Because the issue of preemption by the MDA hinges on whether the state-law claim is based on requirements that are parallel to, rather than different from or in addition to, FDA regulations, a threshold question on a motion to dismiss is whether the plaintiff has alleged that their claim is based on a violation of federal regulation(s). *See Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 827–32 (W.D. Ky. 2014) (deciding whether plaintiff's claims were sufficiently alleged to be based on violations of federal regulations to pass muster under Rule 8 before deciding whether the claims were preempted). But post-*Riegel*, without clear guidance from the Sixth Circuit,[6] the lower courts have struggled to agree on the degree of specificity required to plead a

[6] In *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440–41 (6th Cir. 2010), the Sixth Circuit found that a plaintiff need not allege violations of device-specific federal regulations, in order to allege a parallel state-law claim where the plaintiff had alleged specific good manufacturing practice ("GMP") regulations. But the case offers limited guidance because the court's analysis was focused on whether GMP regulations are sufficient for purposes of alleging

sufficient parallel claim to avoid preemption. Some courts have required plaintiffs to allege the specific federal requirement that was violated and caused their injuries,[7] while other courts have held plaintiffs to a less stringent standard and required only allegations that their injury was caused by the violation of some federal requirement.[8] These lower court decisions are not totally unreconcilable, however, because there is no question that the courts agree that, at a minimum, to sufficiently plead a claim that avoids preemption, a plaintiff must allege (1) that the medical device violated a federal regulation and (2) how that violation caused plaintiff's injury. *See, e.g.*, *Aaron*

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violation of a federal requirement, not on whether plaintiff pleaded a federal violation with enough specificity. Still, the leading Seventh Circuit case cited *Howard* in concluding that it is not necessary for a plaintiff to plead violation of a device-specific requirement, as a claim based on an alleged violation of a GMP could avoid preemption. *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010).

Then in *White v. Medtronic, Inc.*, 808 F. App'x 290, 295 (6th Cir. 2020), the Sixth Circuit seemed to adopt an approach endorsed by a Tenth Circuit court that would require a plaintiff to identify at least "a single parallel federal statute or regulation." *Id.* (quoting *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340–41 (10th Cir. 2015)). But *White* (and *Caplinger*) are distinguishable from this case because, there, the plaintiff did "not challenge . . . the actual manufacture of [the device] but instead [sought] relief pursuant to state law claims challenging [the defendants'] alleged promotion of the off-label use of the device." *White*, 808 F. App'x at 295. And the court held that the plaintiff failed to allege a parallel requirement because the FDCA embraces off-label use of medical devices. *See id.* at 295–96; *see also White v. Medtronic, Inc.*, No. 18-11590, 2019 WL 1339613, at *3–4 (E.D. Mich. Feb. 20, 2019) (outlining each count of the complaint). "Thus, *White* dealt with the inexistence of a parallel federal requirement rather than the failure to adequately plead a violation of a parallel federal requirement." *Kiser v. Terumo Med. Corp.*, No. 2:21-cv-69, 2021 WL 4356044, at *5 n.5 (E.D. Tenn. Sept. 23, 2021).

[7] *E.g.*, *Schmidt v. Bos. Sci. Corp.*, No. 5:15-cv-488, 2016 WL 1274824, *3 (N.D. Ohio Mar. 31, 2016) ("Armed with the Supreme Court's ruling in *Reigel*, courts have held that [p]arallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that [the] defendant violated a particular federal specification referring to the device at issue." (internal quotation marks and citations omitted)); *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 985 (N.D. Ohio 2017) (same); *Aaron*, 209 F. Supp. 3d at 1009 ("[T]his Court rejects the reduced pleading standard for products liability cases involving FDA Class III medical devices[.]"); *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1033, 1039 (W.D. Ky. 2011) ("The Amended Complaint neither cites any particular federal standard or procedure, nor does it generally state how the alleged defect deviated from a federal standard or procedure. . . . [I]t contains only the most general allegations of product liability, negligence and warranty. . . . In the face of the narrow pleading window required to avoid preemption, [p]laintiff has done virtually nothing.").

[8] *E.g.*, *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 906 (S.D. Ohio 2012) (citing the Supreme Court's decision in *Lohr*, 518 U.S. at 495, for the proposition that "to avoid preemption, the complaint need not define 'the precise contours of [the plaintiff's] theory of recovery,' if it alleges that the defendant has violated FDA regulations" (alteration in original)); *Mories*, 494 F. Supp. 3d at 471 (finding the *Hawkins* relaxed pleading standard persuasive); *Waltenburg*, 33 F. Supp. 3d at 832 (finding the complaint passed muster under Rule 8 even though it "d[id] not make specific reference to the precise PMA requirements allegedly violated" because plaintiffs alleged deviations from federal regulations and how the deviations caused their injuries); *Steiden v. Genzyme Biosurgery*, No. 3:11-cv-441-S, 2012 WL 2923225, at *5 (W.D. Ky. July 18, 2012) (finding without reference to any specific regulation that "the allegation of adulteration based on the occurrence of an immediate adverse reaction in one knee to the injection of Synvisc–One® contains sufficient specificity to satisfy *Iqbal* and *Twombly*.").

v. Medtronic, Inc., 209 F. Supp. 3d 994, 1001 (S.D. Ohio 2016) ("[E]ven were the [c]ourt to apply [a] lower pleading standard . . . several of [p]laintiffs' claims would still be deficient because they are not adequately pleaded even under that standard. . . . Plaintiffs simply do not allege—or provide any factual support for an allegation of—violations of federal law[.]" (citations and internal quotation marks omitted)). To be sure, even cases outside the Sixth Circuit support this minimum pleading requirement.[9]

The Court need not determine at this juncture which line of case law is appropriate because Tice has failed to meet even this minimum pleading requirement. Tice's complaint does not allege that any federal requirements were allegedly violated and caused her injury. In fact, her complaint does not even mention the FDA regulations or standards. Tice alleges that the Spectra SCS "was defective[.]" (Doc. No. 1-1 ¶ 19; *see also id.* ¶¶ 25–27.) But Tice does not allege that the Spectra SCS was defective because it violated some applicable federal regulation. Instead, Tice alleges that the Spectra SCS was defective "due to inadequate warning and/or inadequate clinical trials and inadequate reporting and informed consent to Plaintiff" and "inadequate post marketing warning or instruction[.]" (*Id.* ¶¶ 28–29.[10]) Without any allegations of some violated federal

[9] *See Bass v. Stryker Corp.*, 669 F.3d 501, 511–12 (5th Cir. 2012) ("Although the circuits are not in complete agreement as to what constitutes a sufficient pleading . . . [t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is . . . the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury." (emphasis in original)) (synthesizing different pleading requirements in *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010), *Bausch*, and *Wolicki–Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296 (11th Cir. 2011)).

[10] If anything, these allegations suggest that Tice's state-law claims are preempted to the extent Tice is alleging Boston Scientific was required to conduct more clinical trials or include different warnings than what the FDA deemed sufficient during its MDA review. *See Mories*, 494 F. Supp. 3d at 471, 473 ("[A]n action based on a state law will fail where the state law does not mirror federal requirements or imposes requirements exceeding the MDA statutory ceiling." Thus, "[t]o the extent that [p]laintiff alleges [d]efendant's FDA-approved warnings were themselves inadequate under state law, such claims are preempted").

requirement, Tice's complaint cannot possibly satisfy Rule 8's notice pleading requirements and must be dismissed.[11]

B. Leave to Amend

Having determined that Tice's complaint has not satisfied Rule 8's notice pleading requirement, the Court must decide whether to grant Tice's request for leave to amend her complaint. (Doc. No. 9, at 15.) Boston Scientific contends that this Court should deny Tice's request to amend her complaint because all of Tice's claims are preempted and, thus, amendment would be futile. (Doc. No. 10, at 11.)

Leave to amend should be "freely give . . . when justice so requires." Fed. R. Civ. P. 15(a). The decision whether to permit an amendment is committed to the discretion of the trial court. *See Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 330–32, 91 S. Ct. 795, 28 L. Ed. 2d 77 (1971); *Estes v. Ky. Utils. Co.*, 636 F.2d 1131, 1133 (6th Cir. 1980). The trial court's discretion is, however, "limited by Fed. R. Civ. P. 15(a)'s liberal policy of permitting amendments to ensure the determination of claims on their merits." *Marks v. Shell Oil Co.*, 830 F.2d 68, 69 (6th Cir. 1987) (citation omitted). Still, leave to amend a complaint "may be denied when the motion is the product of undue delay, bad faith, or dilatory motive, amendment would cause undue prejudice to the opposing party, the plaintiff repeatedly failed to cure deficiencies in the complaint with previous amendments, or amendment of the complaint would be futile." *Springs v. U.S. Dep't of Treasury*, 567 F. App'x 438, 443 (6th Cir. 2014).

The Court finds no evidence, nor does Boston Scientific contend, that Tice's request to amend her complaint is the product of "undue delay, bad faith, or dilatory motive" or that any

[11] Because this Court finds that Tice's complaint must be dismissed for failing to satisfy Rule 8's notice-pleading requirements, the Court need not determine whether the complaint should be dismissed for either of the alternative grounds raised by Boston Scientific in its motion (*i.e.*, preemption by the MDA and abrogation by Ohio Product Liability Act). (Doc. No. 4 ¶¶ 1–2.)

amendment would cause "undue prejudice" to Boston Scientific. Nor is there any evidence that Tice "repeatedly failed to cure deficiencies in the complaint with previous amendments" because there is no indication in the record that Tice has made any previous amendments to her complaint.

Further, the Court cannot say with the record and case law before it that an amendment would be futile. Although Tice's complaint fails to allege any violations of federal law, her opposition brief contends that her claims are premised on violations of federal law that are parallel to her state-law causes of action. (Doc. No. 9, at 8–9.) For example, she contends that her failure to warn claim is "premised upon [d]efendant's failure to file adverse event reports with the FDA[,]" while other claims "are based on . . . manufacturing defects resulting from violations of federal regulations." (*Id.* at 9.) While contentions made in her opposition brief cannot serve to amend the complaint, they suggest that Tice may be able to plead sufficient facts to support her purported claims in an amended complaint.

In light of Rule 15(a)'s mandate that leave should be "freely" given, the Court rules that "justice so requires" the Court to allow Tice leave to amend her complaint to the extent—and only to the extent—that she complies with Rule 8[12] and can properly allege state-law claims based on violation(s) of some federal requirement.

IV. CONCLUSION

For the reasons set forth herein, Boston Scientific's motion to dismiss is GRANTED but Tice is GRANTED LEAVE TO AMEND her complaint to the extent she can allege any sufficient parallel claim(s). Tice shall have until February 6, 2023, to file an amended complaint. Having

[12] The Court appreciates that Tice's original complaint was filed in state court, but any amended complaint must adhere to all federal and local rules concerning the proper form of pleadings.

given Tice this opportunity to amend her complaint, the Court cautions Tice that further motions for leave to amend will be disfavored.

IT IS SO ORDERED.

Dated: January 23, 2023

HONORABLE SARA LIOI
UNITED STATES DISTRICT JUDGE